Complete Summary

GUIDELINE TITLE

Vaccine preventable STDs. Sexually transmitted diseases treatment guidelines 2002.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Vaccine preventable STDs. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):59-64.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Hepatitis A
- Hepatitis B

GUIDELINE CATEGORY

Diagnosis
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine

Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the 1998 Guidelines for Treatment of Sexually Transmitted Diseases (MMWR 1998;47[No. RR-1])
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases (STDs)
- To present updated recommendations for the prevention and treatment of hepatitis A and hepatitis B

TARGET POPULATION

Hepatitis A

- Men who have sex with men (MSM), including those who report having minimal or no current sexual activity;
- Illegal drug users (both injection and non-injection drug users); and
- Persons with chronic liver disease, including persons with chronic hepatitis B virus and hepatitis C virus infection who have evidence of chronic liver disease

Hepatitis B

- All persons who attend sexually transmitted disease (STD) clinics who have not been previously vaccinated.
- Persons with history of a STDs
- Persons who have had multiple sex partners
- Individuals who have had sex with an injection-drug user
- Sexually active men who have sex with men;
- Persons engaging in illegal drug use
- Household members, sex partners, and drug-sharing partners of a person with chronic hepatitis B virus infection
- Persons on hemodialysis, persons receiving clotting factor concentrates, or persons who have occupational exposure to blood.
- All persons who have not been previously vaccinated who receive services in drug treatment programs and long-term correctional facilities.
- All pregnant women receiving STDs services

INTERVENTIONS AND PRACTICES CONSIDERED

Note from the National Guideline Clearinghouse and the Centers for Disease Control and Prevention: These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

Hepatitis A

Prevention

1. Hepatitis A vaccine (HAVRIX, VAQTA)
2. Immune globulin (IG) for intramuscular administration

Diagnosis

1. Serologic testing for presence of immunoglobulin M (IgM) antibody to hepatitis A virus

Treatment

1. Supportive care
2. Hospitalization

Hepatitis B

Prevention

1. Hepatitis B immunoglobulin (HBIG)
2. Hepatitis B vaccine (Recombivax, Energix-B)

Diagnosis

1. Serological tests for hepatitis B surface antigen (HBsAg) or presence of immunoglobulin M antibody to hepatitis B core antigen (anti-HBc) or antibody to hepatitis B surface antigen (anti-HBs)

Treatment/Management

1. Confirm suspected acute or chronic hepatitis B virus infection with laboratory testing
2. Referral for medical follow-up
3. Referral for treatment of chronic infection
4. Vaccination and postexposure prophylaxis for contacts
5. Antiviral agents, such as alpha-interferon or lamivudine
6. Special considerations for pregnant women and HIV-infected persons

MAJOR OUTCOMES CONSIDERED

- Prevalence of hepatitis A and hepatitis B infection
- Risk for hepatitis A and hepatitis B infection

- Risk for chronic infection
- Risk for death from chronic liver disease
- Development of protective antibody response
- Prevention of transmission

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Beginning in 2000, Centers for Disease Control and Prevention (CDC) personnel and professionals knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed literature (i.e., published abstracts and peer-reviewed journal articles) concerning each of the major STDs, focusing on information that had become available since publication of the 1998 Guidelines for Treatment of Sexually Transmitted Diseases. Background papers were written and tables of evidence constructed summarizing the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. A draft document was developed on the basis of the reviews.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The most effective means to prevent transmission of infectious diseases, including STDs, is through preexposure immunization. Vaccines are available for prevention of hepatitis A virus (HAV) and hepatitis B virus (HBV), both of which can be transmitted sexually. Vaccines are under development or are undergoing clinical trials for other STDs, including human immunodeficiency virus (HIV), human papillomavirus (HPV), and herpes simplex virus (HSV); however, current efforts regarding vaccination focus largely on integrating use of currently available vaccines into STD prevention and treatment activities.

Every person seeking treatment for an STD should be considered a candidate for hepatitis B vaccination, and some persons (e.g., men who have sex with men [MSM] and injection-drug users) should be considered for hepatitis A vaccination. Evaluation for vaccination is most effectively done through a screening and education process that both inquires about risk factors for infection (e.g., sex partners and use of illegal drugs), educates patients about the importance of vaccination, and excludes persons who are not candidates for vaccination (e.g., laboratory confirmed diagnosis of infection and previous vaccination).

Although it is uncommon, patients may present with signs, symptoms, or laboratory findings of acute or chronic viral hepatitis. When this occurs, a precise diagnosis must be made and appropriate clinical services provided, including postexposure immunization of contacts and medical referral.

Hepatitis A

Hepatitis A, caused by infection with HAV, has an incubation period from time of exposure to onset of symptoms of approximately 4 weeks (range: 15--50 days). HAV replicates in the liver and is shed in high concentrations in feces from 2 weeks before to 1 week after the onset of clinical illness. HAV is most commonly

transmitted by the fecal-oral route. Although viremia occurs early in infection and can persist for several weeks after onset of symptoms, bloodborne transmission of HAV is uncommon.

HAV infection produces a self-limited disease that does not result in chronic infection or chronic liver disease. However, 10%--15% of patients may experience a relapse of symptoms during the 6 months after acute illness. Acute liver failure from hepatitis A is rare (0.3% overall case-fatality rate), but occurs more frequently in older persons (1.8% case fatality rate in adults >50 years of age) and persons with underlying chronic liver disease. The risk for symptomatic infection is directly related to age, with >80% of adults having symptoms compatible with acute viral hepatitis and most children having either asymptomatic or unrecognized infection. Antibody produced in response to HAV infection persists for life and confers protection against reinfection.

Approximately 33% of the U.S. population has serologic evidence of prior HAV infection, which increases directly with age and reaches 75% among persons aged >70 years. Most cases of hepatitis A result from person-to-person transmission during community-wide outbreaks. The most frequently reported source of infection (12%--26%) is either household or sexual contact with a person who had hepatitis A. In addition, outbreaks regularly occur among users of injection and non-injection drugs and among MSM. In the United States, up to 10% of reported cases of HAV occur among persons reporting these behaviors. Approximately 50% of persons with hepatitis A do not have an identified source for their infection.

Hepatitis A, like other enteric infections, can be transmitted during sexual activity. Recent outbreaks of hepatitis A among MSM have occurred in urban areas in the United States. Although some studies have associated having a greater number of sex partners, frequent oral-anal contact, insertive anal intercourse, or serologic evidence of other STDs with HAV infection, other studies have not found specific risk factors for infection.

Unlike persons with most other STDs, HAV-infected persons are infectious for only a relatively brief period of time. However, many sexual practices facilitate fecal-oral transmission of HAV, and inapparent fecal contamination is commonly present during sexual intercourse. Measures typically used to prevent the transmission of other STDs (e.g., use of condoms) do not prevent HAV transmission, and maintenance of "good personal hygiene" has not been successful in interrupting outbreaks of hepatitis A. Vaccination is the most effective means of preventing HAV transmission among persons at risk for sexual transmission of this virus and among persons who use injection and non-injection illegal drugs, many of whom may seek services in STD clinics.

Diagnosis

The diagnosis of hepatitis A cannot be made on clinical grounds alone and requires serologic testing, which is available commercially. The presence of immunoglobulin M (IgM) antibody to HAV is diagnostic of acute HAV infection. A positive test for total anti-HAV indicates immunity to HAV infection but does not differentiate acute from past HAV infection. Tests can be positive after hepatitis A vaccination.

Treatment

Patients with hepatitis A usually require only supportive care, with no restrictions in diet or activity. Hospitalization may be necessary for patients who become dehydrated because of nausea and vomiting and for patients with signs or symptoms of acute liver failure. Medications that might cause liver damage or are metabolized by the liver should be used with caution among persons with HAV.

Prevention

Two products are available for the prevention of hepatitis A: hepatitis A vaccine (see table 2 in the original guideline document for recommended dose and schedule) and immune globulin (IG) for intramuscular (IM) administration. Inactivated hepatitis A vaccines are prepared from formalin-inactivated, cell-culture-derived HAV and have been available in the United States since 1995 for persons aged >2 years. Administered in a two-dose series, these vaccines induce protective antibody levels in virtually all adults. By 1 month after the first dose, 94%--100% of adults have protective antibody levels; 100% of adults develop protective antibody following a second dose. In randomized controlled trials, the equivalent of one dose of hepatitis A vaccine administered before exposure has been 94%--100% effective in preventing clinical hepatitis A. Kinetic models of antibody decline indicate that protective levels of antibody persist for at least 20 years.

A combined hepatitis A and B vaccine has been developed for adults. When administered on a 0-, 1-, 6-month schedule, the vaccine has equivalent immunogenicity to that of the monovalent vaccines.

IG is a sterile solution of concentrated immunoglobulins prepared from pooled human plasma processed by cold ethanol fractionation. In the United States, IG is produced only from plasma that has tested negative for HBV, antibody to HIV, and antibody to hepatitis C virus (HCV). In addition, the manufacturing process must either include a viral inactivation step or the final product must test negative for HCV ribonucleic acid (RNA). When administered before or within 2 weeks after exposure to HAV, IG is $\geq$85% effective in preventing hepatitis A.

Preexposure Immunization

Persons in the following groups should be offered hepatitis A vaccine:

- MSM, including those who report having minimal or no current sexual activity;
- illegal drug users (both injection and non-injection drug users); and
- persons with chronic liver disease, including persons with chronic HBV and HCV infection who have evidence of chronic liver disease.

Hepatitis A vaccine currently is available for children and adolescents aged <19 years through the Vaccines for Children (VFC) program (tel: 800-232-2522).

Prevaccination Serologic Testing for Susceptibility

Screening for HAV infection may be cost-effective in populations where the prevalence of infection is likely to be high (e.g., older persons and persons born in areas of high HAV endemicity). The potential cost-savings of testing should be weighed against the likelihood that testing will interfere with initiating vaccination. Vaccination of a person who is already immune is not harmful.

Postvaccination Serologic Testing

Postvaccination serologic testing is not indicated because most persons respond to vaccine. In addition, the commercially available serologic test is not sensitive enough to detect the low, but protective, levels of antibody produced by vaccination.

Postexposure Prophylaxis

Previously unvaccinated persons exposed to HAV (e.g., through household or sexual contact or by sharing illegal drugs with a person who has hepatitis A) should be administered a single IM dose of IG (0.02 mL/kg) as soon as possible, but not >2 weeks after exposure. Persons who have had one dose of hepatitis A vaccine at least 1 month before exposure to HAV do not need IG. If hepatitis A vaccine is recommended for a person receiving IG, it can be administered simultaneously at a separate anatomic injection site. The use of hepatitis A vaccine alone is not recommended for postexposure prophylaxis.

Special Considerations

Limited data indicate that vaccination of HIV-infected persons results in lower seroprotection rates and antibody concentrations. Antibody response may be directly related to CD4+ levels.

Hepatitis B

Hepatitis B is caused by infection with HBV. The incubation period from time of exposure to onset of symptoms is 6 weeks to 6 months. HBV is hepatotropic, is found in highest concentrations in the blood, and is found in lower concentrations in other body fluids (e.g., semen, vaginal secretions, and wound exudates). HBV infection can be self-limited or chronic. In adults, only 50% of acute HBV infections are symptomatic, and about 1% of cases result in acute liver failure and death. Risk for chronic infection is associated with age at infection: about 90% of infected infants and 60% of infected children aged <5 years become chronically infected compared with 2%--6% of adults. Among persons with chronic HBV infection, the risk of death from cirrhosis or hepatocellular carcinoma is 15%--25%.

In the United States, an estimated 181,000 persons were infected with HBV in 1998, and about 5,000 deaths occurred from HBV-related cirrhosis or hepatocellular carcinoma. An estimated 1.25 million people are chronically infected with HBV, serve as a reservoir for infection, and are at increased risk for death from chronic liver disease.

HBV is efficiently transmitted by percutaneous or mucous membrane exposure to infectious body fluids. Sexual transmission among adults accounts for most HBV infections in the United States. In the 1990s, transmission among heterosexual partners accounted for about 40% of infections, and transmission among MSM accounted for another 15% of infections. The most common risk factors for heterosexual transmission include having multiple sex partners (i.e., more than one partner in a 6-month period) or a recent history of an STD. Risk factors for infection among MSM include having multiple sex partners, engaging in unprotected receptive anal intercourse, and having a history of other STDs. Changes in sexual practices among MSM to prevent HIV infection have resulted in a lower risk for HBV infection than that observed in the late 1970s, when studies found up to 70% prevalence of HBV markers among adult MSM. Recent surveys of young MSM (aged 15--22 years) indicated that 6%--13% of participants had evidence of HBV infection, whereas 3%--27% had evidence of having been immunized against hepatitis B.

Among persons with acute hepatitis B, up to 70% have previously received care in settings where they could have been vaccinated (e.g., STD clinics, drug treatment programs, and correctional facilities). A 1997 survey of STD clinics demonstrated that hepatitis B vaccine was routinely offered in only 5% of these settings.

Diagnosis

The diagnosis of acute or chronic HBV infection cannot be made on clinical grounds, but requires serologic testing (see table 3 of the original guideline document). Hepatitis B surface antigen (HBsAg) is present in either acute or chronic infection. The presence of IgM antibody to hepatitis B core antigen (IgM anti-HBc) is diagnostic of acute HBV infection. Antibody to HBsAg (anti-HBs) is produced following a resolved infection and is the only HBV antibody marker present following immunization. The presence of HBsAg with a negative test for IgM anti-HBc is indicative of chronic HBV infection. The presence of anti-HBc may indicate either acute, resolved, or chronic infection.

Treatment

Laboratory testing should be used to confirm suspected acute or chronic HBV infection, and infected persons should be referred for medical follow-up and possible treatment of chronic infection. In addition, contacts should be vaccinated (see "Exposure to Persons who have Acute Hepatitis B" section below) and receive postexposure prophylaxis. No specific therapy is available for persons with acute HBV infection; treatment is supportive.

Antiviral agents (i.e., alpha-interferon or lamivudine) are available for treatment of persons with chronic hepatitis B. To determine the likelihood of response to treatment, an initial evaluation is required to determine the status of the chronic HBV infection and the extent of liver disease. For this reason, treatment should be offered by health-care professionals with experience in the treatment of hepatitis B.

Prevention

Two products have been approved for hepatitis B prevention: hepatitis B immune globulin (HBIG) and hepatitis B vaccine. HBIG is prepared from plasma known to contain a high titer of anti-HBs and is used for postexposure prophylaxis. The recommended dose of HBIG for children and adults is 0.06 mL/kg. The dose is 0.5 mL to prevent perinatal HBV infection among infants born to HBsAg-positive mothers.

Hepatitis B vaccine uses HBsAg produced in yeast by recombinant deoxyribonucleic acid (DNA) technology and provides protection from HBV infection when used for both preexposure immunization and postexposure prophylaxis. The two available monovalent hepatitis B vaccines for use in adolescents and adults are Recombivax HB® and Engerix-B.

The recommended vaccine dose varies by product and age of recipient (see table 4 of the original guideline document). Vaccine should be administered IM in the deltoid muscle and can be administered simultaneously with other vaccines. Many vaccination schedules have been used for both adults and adolescents. A two-dose schedule has been approved for adolescents aged 11--15 years using the adult dose of Recombivax HB®. If the vaccination series is interrupted after the first or second dose of vaccine, the missed dose should be administered as soon as possible. The series does not need to be restarted if a dose has been missed.

In adolescents and healthy adults aged <40 years, approximately 50% develop a protective antibody response (anti-HBs >10 mIU/mL) after the first vaccine dose, 70% after the second, and >90% after the third dose. Because relatively high rates of protection are achieved following each vaccine dose, hepatitis B vaccination should be initiated even if completion of the series cannot be ensured. Because most fully vaccinated persons have long-lasting protection from HBV infection, periodic testing to determine antibody levels in immune competent persons is not necessary, and booster doses of vaccine are not recommended.

Hepatitis B vaccine has been shown to be safe; more than 20 million adolescents and adults have been vaccinated in the United States. The vaccine is well tolerated by most recipients. Pain at the injection site or low-grade fever are reported by a minority of recipients. Anaphylaxis is estimated to occur in one in 600,000 doses of vaccine administered; no deaths have been reported following anaphylaxis. Hepatitis B vaccine has not been associated with multiple sclerosis, diabetes, or other autoimmune or neurologic diseases in any controlled epidemiologic study. Vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of hepatitis B vaccine and in persons with a known anaphylactic reaction to yeast.

The Centers for Disease Control and Prevention (CDC)'s national immunization strategy to eliminate transmission of HBV infection includes a) prevention of perinatal infection through maternal HBsAg screening and postexposure prophylaxis of at-risk infants, b) universal infant immunization, c) universal immunization of previously unvaccinated adolescents aged 11--12 years, and d) vaccination of adolescents and adults at increased risk for infection. Although high immunization coverage rates have been achieved among infants and younger adolescents, hepatitis B incidence rates remain high because most infections now occur in adults. Although the cost of vaccine remains a barrier to adult vaccination, vaccine purchase and provider reimbursement should not be a barrier

for vaccination of adolescents aged <19 years, who may be eligible for free vaccine under the Vaccines for Children (VFC) program (tel: 800-232-2522).

Preexposure Immunizations

Hepatitis B vaccine is recommended for all persons who attend STD clinics who have not been previously vaccinated. In the non-STD clinic setting, the following persons should be vaccinated: a) persons with history of an STD, persons who have had multiple sex partners, those who have had sex with an injection-drug user, and sexually active MSM; b) persons engaging in illegal drug use; c) household members, sex partners, and drug-sharing partners of a person with chronic HBV infection; and d) persons on hemodialysis, persons receiving clotting factor concentrates, or persons who have occupational exposure to blood. In addition, hepatitis B vaccine should be offered to all persons who have not been previously vaccinated who receive services in drug treatment programs and long-term correctional facilities.

Prevaccination Antibody Screening

Based on the current cost of hepatitis B vaccine, revaccination serologic testing may be cost-effective in adult populations with a high prevalence of HBV infection (>2% HBsAg positive or >30% anti-HBc positive). However, prevaccination testing is not cost-effective in any adolescent populations. Adult populations with high prevalence of HBV infection include injection-drug users, MSM, sexual contacts of persons with chronic HBV infection, and persons from countries with endemic HBV infection. When testing is performed, anti-HBc is the test of choice. Testing should not be a barrier to vaccination of susceptible persons, especially in populations that are difficult to access, and the first dose of vaccine should be administered at the same time that serologic testing is initiated.

As hepatitis B vaccination becomes more widespread, more persons will present with a history of vaccination and most will not have a personal vaccination record. However, serologic testing in persons with a history of previous hepatitis B vaccination may not be helpful because of the loss of detectable antibody. Without a vaccination record, obtaining a careful history (e.g., number of doses, schedule, and age at immunization) is the only way to determine if the person most likely received the complete hepatitis B vaccine series. Administration of additional doses of vaccine beyond the three-dose series is not harmful.

Postexposure Prophylaxis

Exposure to Persons Who Have Acute Hepatitis B

Sex Contacts. Previously unvaccinated sex partners of persons with acute hepatitis B should receive postexposure immunization with HBIG and hepatitis B vaccine within 14 days after the most recent sexual contact. HBIG has been shown to be required for effective postexposure protection in this setting. Administration of vaccine with HBIG in this setting confers long-term protection in the event the person with acute hepatitis B becomes chronically infected; simultaneous administration of HBIG and hepatitis B vaccine does not reduce vaccine effectiveness. Testing sex partners for susceptibility to HBV infection

(anti-HBc) can be considered if it does not delay postexposure immunization beyond 14 days.

Nonsexual Household Contacts. Nonsexual household contacts of patients who have acute hepatitis B are not at increased risk for infection unless they have other risk factors or are exposed to the patient's blood (e.g., by sharing a toothbrush or razor blade). However, vaccination of household contacts is encouraged, especially for children and adolescents. If the patient with acute hepatitis B becomes chronically infected (i.e., remains HBsAg-positive after 6 months), all household contacts should be vaccinated.

Exposure to Persons Who Have Chronic HBV Infection

Most HBsAg-positive persons are identified during routine screening (e.g., blood donation and prenatal evaluation) or clinical evaluation. Active postexposure prophylaxis with hepatitis B vaccine alone is recommended for sex or needle-sharing partners and non-sexual household contacts of persons with chronic HBV infection. Because identifying the time of the last contact can be difficult, hepatitis B vaccination provides both preexposure and postexposure protection. Although the effectiveness of active postexposure immunization has not been evaluated for sex contacts of persons with chronic HBV infection, it provides high-level protection (90%) against perinatal HBV infection, where the intensity of exposure is greater than that among household or sex contacts of chronically infected persons.

Postvaccination testing (anti-HBs) should be considered for sex partners of persons with chronic HBV infection. Although most persons are expected to respond to vaccination, those found to be antibody-negative should receive a second, complete vaccination series. Those persons found to be antibody-negative after revaccination should be counseled about abstinence and the use of other methods to protect themselves from sexual HBV transmission.

Special Considerations

Pregnancy

All pregnant women receiving STD services should be tested for HBsAg, regardless of whether they have been previously tested. If positive, this test result should be reported to state perinatal immunization or HBV prevention programs to ensure proper case management of the mother and appropriate postexposure immunization of her at-risk infant. HBsAg-negative pregnant women seeking STD treatment who have not been previously vaccinated should receive hepatitis B vaccine, as pregnancy is not a contraindication to vaccination.

HIV Infection

HBV infection in HIV-infected persons is more likely to result in chronic HBV infection. HIV infection also can impair the response to hepatitis B vaccine. Therefore, HIV-infected persons who are vaccinated should be tested for anti-HBs 1--2 months after the third vaccine dose. Revaccination with three more doses should be considered for persons who do not respond initially to vaccination.

Those who do not respond to additional doses should be advised that they might remain susceptible to HBV infection and should be counseled in the use of methods to prevent HBV infection.

Victims of Sexual Assault

Studies have not determined the frequency with which HBV infection occurs following sexual abuse or rape. Fully vaccinated victims of sexual assault are protected from HBV infection and do not need further doses. For a victim who is not fully vaccinated, the vaccine series should be completed as scheduled. Unvaccinated persons in this setting should be administered active postexposure prophylaxis (i.e., vaccine alone) upon the initial clinical evaluation. Unless the offender is known to have acute hepatitis B, HBIG is not required.

Because sexual abuse of children frequently occurs over a prolonged period of time, the last exposure is often difficult to determine. However, when sexual abuse is identified, hepatitis B vaccination should be initiated in previously unvaccinated children.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

Throughout the 2002 guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal Clinical Infectious Diseases.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis, management and treatment of patients who have viral hepatitis A or B
- Decreased rates of infection of viral hepatitis A or B:
- In randomized controlled trials, the equivalent of one dose of hepatitis A vaccine administered before exposure has been 94%-100% effective in preventing clinical hepatitis A.
- In adolescents and healthy adults aged <40 years, approximately 50% develop a protective response after the first hepatitis B vaccine dose, 70% after the second, and > 90% after the third dose.
- Decreased morbidity and mortality due to viral hepatitis A or B infection and complications of infection, such as chronic hepatitis

- Reduction in the risk of perinatal infection among infants born to hepatitis B-infected mothers

POTENTIAL HARMS

Hepatitis B

Pain at the injection site or low-grade fever are reported by a minority of recipients. Anaphylaxis is estimated to occur in one in 600,000 doses of vaccine administered; no deaths have been reported following anaphylaxis. Hepatitis B vaccine has not been associated with multiple sclerosis, diabetes, or other autoimmune or neurologic diseases in any controlled epidemiologic study.

CONTRAINDICATIONS

CONTRAINDICATIONS

Hepatitis B vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of hepatitis B vaccine and in persons with a known anaphylactic reaction to yeast.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These recommendations were developed in consultation with public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases (STDs). They are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities. When using these guidelines, the disease prevalence and other characteristics of the medical practice setting should be considered. These recommendations should be regarded as a source of clinical guidance and not as standards or inflexible rules. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are important in sexually transmitted disease/human immunodeficiency virus (STD/HIV) prevention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Vaccine preventable STDs. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2002 May 10;51(RR-6):59-64.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1993 (revised 2002 May 10)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

These guidelines for the treatment of patients who have sexually transmitted diseases (STDs) were developed by the Centers for Disease Control and Prevention (CDC) after consultation with a group of professionals knowledgeable in the field of STDs who met in Atlanta on September 26--28, 2000.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The information in this report updates the "1998 Sexually Transmitted Diseases Treatment Guidelines" (MMWR 1998;47[No. RR-1]).

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML version
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Workowski KA, Levine WC, Wasserheit JN. U.S. Centers for Disease Control and Prevention guidelines for the treatment of sexually transmitted diseases: an opportunity to unify clinical and public health practice. Ann Intern Med. 2002 Aug 20;137(4):255-62. Electronic copies: Available through Annals of Internal Medicine Online.
- Sexually Transmitted Diseases Treatment Guidelines 2002 for PDA or Palm OS. Available from the CDC National Prevention Information Network (NPIN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 5, 2002.

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